OMB No. 0990-0263
Approved for use through 07/31/2005

Protection of Human Subjects
Assurance Identification/IRB Certification/Declaration of Exemption
(Common Rule)

Policy: Research activities involving human subjects may not be conducted or supported by the Departments and Agencies adopting the Common Rule (56FR28003, June 18, 1991) unless the activities are exempt from or approved in accordance with the Common Rule. See section 101(b) of the Common Rule for exemptions. Institutions submitting applications or proposals for support must submit certification of appropriate Institutional Review Board (IRB) review and approval to the Department or Agency in accordance with the Common Rule.

Institutions must have an assurance of compliance that applies to the research to be conducted and should submit certification of IRB review and approval with each application or proposal unless otherwise advised by the Department or Agency.

1. Request Type	2. Type of Mechanism	3. Name of Federal Department or Agency and, if known, Application or Proposal Identification No.
☐ ORIGINAL ☐ CONTINUATION ☑ EXEMPTION	☑ GRANT ☐ CONTRACT ☐ FELLOWSHIP ☐ COOPERATIVE AGREEMENT ☐ OTHER:_____	
4. Title of Application or Activity		5. Name of Principal Investigator, Program Director, Fellow, or Other

6. Assurance Status of this Project *(Respond to one of the following)*

☐ This Assurance, on file with Department of Health and Human Services, covers this activity:
Assurance Identification No._____, the expiration date_____ IRB Registration No. _____

☐ This Assurance, on file with *(agency/dept)*_____, covers this activity.
Assurance No._____, the expiration date_____ IRB Registration/Identification No._____*(if applicable)*

☐ No assurance has been filed for this institution. This institution declares that it will provide an Assurance and Certification of IRB review and approval upon request.

☐ Exemption Status: Human subjects are involved, but this activity qualifies for exemption under Section 101(b), paragraph_____.

7. Certification of IRB Review (Respond to one of the following IF you have an Assurance on file)

☐ This activity has been reviewed and approved by the IRB in accordance with the Common Rule and any other governing regulations.
by: ☐ Full IRB Review on (date of IRB meeting) _____ or ☐ Expedited Review on (date)
☐ If less than one year approval, provide expiration date _____

[ ] This activity contains multiple projects, some of which have not been reviewed. The IRB has granted approval on condition that all projects covered by the Common Rule will be reviewed and approved before they are initiated and that appropriate further certification will be submitted.

8. Comments

9. The official signing below certifies that the information provided above is correct and that, as required, future reviews will be performed until study closure and certification will be provided.	10. Name and Address of Institution
11. Phone No. *(with area code)* 12. Fax No. *(with area code)* 13. Email:	
14. Name of Official	15. Title
16. Signature	17. Date

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Instructions for Protection of Human Subjects Assurance Identification/ IRB Certification/Declaration of Exemption Form

Box 1: Check Request Type: Original (New Award), Continuation, or Exemption (Do Not Use)

Box 2: Check Type of Award Mechanism: Grant, Contract, Cooperative Agreement, Fellowship , Other

Box 3: Insert **National Institute of Justice** as Name of Federal Department or Agency

Box 4: List Title of Application

Box 5: List Name as requested

Box 6: For Assurance Status of this Project, four options for response are provided:

Option 1) Assurance on file with HHS and IRB has approved. (NOTE: The Federalwide Assurance number, expiration date, and IRB registration number must be provided here. The Certification of IRB review and approval must also be provided.)

Option 2) Assurance on file with another Federal agency or department and IRB has approved. (NOTE: The Assurance number, expiration date, and IRB registration number must be provided here. The Certification of IRB review and approval must also be provided.)

Option 3) No Assurance has been filed. The institution declares that it will provide and Assurance and Certification of IRB review and approval upon request.

All applicants should check the third option unless the applicant has already submitted this research application to and received approval or exemption from an IRB with an Assurance on file.

Option 4) Exemption Status: Use this option only if one of the exemptions listed in the regulation applies. Your IRB approval of exemption memo must be provided, or you may apply for an exemption from NIJ. See Exemption Request Information.

Box 7: For Certification of IRB Review, if an Assurance is on file (that is, if Option 1 or 2 was selected in Box 6), two options for response are provided:

Option 1) Select this option if IRB approval was provided for this project, provide the date and indicate whether the approval was the result of a Full or Expedited IRB Review.

Option 2) Select this option if this project has not yet received IRB certification.

Box 8: Comments: If applicable, indicate that "This project will not involve human subjects."

Boxes 10-17: Complete as indicated. The signing official must be a representative of the applicant institution, i.e., Director, Office of Sponsored Research or Chair, IRB.